

**Substitute for form 1449/RTO**

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

**(Use as many sheets as necessary)**

Shee

1

9

1

**Complete if Known**

Application Number	10/705,441
Filing Date	11/10/03
First Named Inventor	Cagle et al.
Art Unit	1623
Examiner Name	
Attorney Docket Number	2399 F US

U. S. PATENT DOCUMENTS

## **FOREIGN PATENT DOCUMENTS**

**Examiner  
Signature**

/Ruth Davis/

Date Considered

01/04/2007

**'EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **<sup>1</sup>** Applicant's unique citation designation number (optional). **<sup>2</sup>** See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. **<sup>3</sup>** Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). **<sup>4</sup>** For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. **<sup>5</sup>** Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. **<sup>6</sup>** Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

1

of

4

## Complete If Known

Application Number	10/705,441
Filing Date	11/10/03
First Named Inventor	Gerald Cagle
Art Unit	
Examiner Name	

Attorney Docket Number

2399 F US

## U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
RD	A1	US- 2,914,442	11/24/1959	Halpern	
	A2	US- 3,422,186	01/14/1969	Sasmor	
	A3	US- 4,556,554	12/03/1985	Calvo	
	A4	US- 4,559,322	12/17/1985	Maltz	
	A5	US- 4,769,171	09/06/1988	Harless	
	A6	US- 4,895,875	01/23/1990	Winston	
	A7	US- 4,921,630	05/01/1990	Bhatia	
	A8	US- 5,296,472	03/22/1994	Sanchez et al.	
	A9	US- 5,380,711	01/10/1995	Sanchez et al.	
	A10	US- 5,403,598	04/04/1995	Beck et al.	
	A11	US- 5,474,209	12/12/1995	Vallet Mas et al.	
	A12	US- 5,480,658	01/02/1996	Melman	
	A13	US- 5,604,190	02/18/1997	Chowhan et al.	
	A14	US- 5,782,345	07/21/1998	Guasch et al.	
	A15	US- 5,954,682	09/21/1999	Petrus	
	A16	US- 6,069,120	05/30/2000	Asgharian et al.	
V	A17	US- 6,093,417	07/25/2000	Petrus	
	A18	US- 6,139,646	10/31/2000	Asgharian	
	A19	US- 6,228,323	05/08/2001	Asgharian et al.	

## FOREIGN PATENT DOCUMENTS

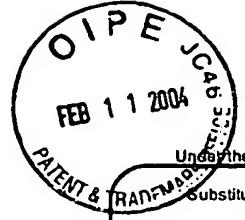
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>4</sup>
		Country Code <sup>3</sup> "Number" "Kind Code <sup>5</sup> (if known)				
RD	A20	GB 903,256	08/15/1962	Halpern		
RD	A21	EP 0 747 044	04/18/2001	Maugendre	Page 6	
	A22					
	A23					
	A24					
	A25					

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Volume 4, No. 1, January

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

*(Use as many sheets as necessary)*

Sheet 2 of 4

**Complete If Known**

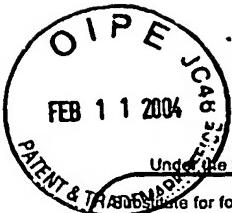
Application Number	10/705,441
Filing Date	11/10/03
First Named Inventor	Gerald Cagle
Art Unit	
Examiner Name	
Attorney Docket Number	2399 F US

**Examiner Signature** \_\_\_\_\_ **Date Considered** \_\_\_\_\_

<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>2</sup>Applicant's unique citation designation number (optional). <sup>3</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 801.04. <sup>4</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>5</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup>Kind of document by appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>7</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

3

of

4

Complete if Known	
Application Number	10/705,441
Filing Date	11/10/03
First Named Inventor	Gerald Cagle
Art Unit	
Examiner Name	
Attorney Docket Number	2399 F US

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
RD	C1	J. G. FRASER, "The efficacy of wax solvents: in vitro studies and a clinical trial." J. Laryngol. Otol., 1970, Vol. 84, pp. 1055-1064	
	C2	IMS Drug Monographs, File Drugmonog2, October 11, 2000, 5 pages.	
	C3	M. A. MANDOUR, ET AL., "Histological and histochemical study of the activity of ceruminous glands in normal and excessive wax accumulation." pp. 1075-1085	
	C4	SHIGEKI SHICHIJO ET AL., "Carbohydrate Composition of Glycopeptides from the Human Cerumen." Biochemical Medicine 22, pp. 256-263 (1979)	
	C5	A. C. ROBINSON ET AL., "The efficacy of ceruminolytics: everything old is new again." The Journal of Otolaryngology 18:6, pp. 263-267, 1989	
	C6	JEFFREY WEINBERGER ET AL., "Steroid sulfatase activity in the skin of the external ear canal." The Journal of Otolaryngology 19:2, 1990, pp. 83-85	
	C7	BRIAN BINGHAM ET AL., "Cerumen: An Etymological and Historical Snippet." Journal of Otolaryngology 20:1, p. 65, 1991	
	C8	JERRY B. NAIBERG ET AL., "Swirls, wrinkles and the whole ball of wax (The source of keratin in cerumen)." The Journal of Otolaryngology 21:2, 1992, pp. 142-148	
	C9	ISABELLE OKUDA ET AL., "The organic composition of earwax." The Journal of Otolaryngology 20:3, 1991, pp. 212-215	
↓	C10	A. C. ROBINSON ET AL., "Impacted cerumen." The Journal of Otolaryngology, 19:2, 1990, pp. 86-90	

Examiner Signature	Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

4

of

4

Complete If Known	
Application Number	10/705,441
Filing Date	11/10/03
First Named Inventor	Gerald Cagle
Art Unit	
Examiner Name	
Attorney Docket Number	2399 F US

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
RD	D1	A. C. ROBINSON ET AL., "The mechanism of ceruminolysis." The Journal of Otolaryngology 18:6, 1989, pp. 268-273	
	D2	EM KEANE ET AL., "Use of Solvents to Disperse Ear Wax." British Journal of Clinical Practice, Vol 49, No. 2, 1995, pp. 71-72	
	D3	MAX KAMIEN, "Which cerumenolytic?" Australian Family Physician Vol. 28, No. 8, August 1999, pp. 817; 828	
	D4	CHRISTOPHER DRIVER, "Removal of ear wax." Letters to the Editor, Australian Family Physician Vol. 28, No. 12, December 1999, p. 1215	
	D5	"Otucus Enzimatico" Brochure from Laboratorios Cusi S-A. November, 1992. 3 pages	
▼	D6	" Ear Preparations," "Ear Preparations of the British Pharmacopoeia," "Sodium Bicarbonate Ear Drops," and "Sodium Bicarbonate." British Pharmacopoeia 2000, 4 pages	

Examiner Signature	/Ruth Davis/	Date Considered	01/04/2007
--------------------	--------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.88. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.